

**UNITED STATES PATENT & TRADEMARK OFFICE**

Examiner: KANTAMNENI, Shobha      Art Unit: 1617

Re:    Application of:                      BANERJEE, Partha S., et al.  
Serial No.:                                  09/887,496  
Filed:                                        June 22, 2001  
For:                                        **FORMOTEROL/STEROID  
BRONCHODIALATING COMPOSITIONS  
AND METHODS OF USE THEREOF**  
Confirmation No.:                        7707

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

June 27, 2007

Sir:

Further to the Supplemental Information Disclosure Statement submitted on January 13, 2006 and pursuant to M.P.E.P. §609 and 37 C.F.R. §§1.56, 1.97-1.99, Applicants herewith submit form PTO-1449, which lists references of which Applicants are aware for the present application.

This submission does not represent that a search has been made or that no better art exists. While the term "references" is used in citing the documents called to the Examiner's attention herein, Applicants do not make any admission that each or all of them are "prior art" references within the meaning of the statutory and case law.

Applicants reserve the right to contend, where appropriate, that a reference asserted against any claim of the present application is not prior art under the facts and the law.

Applicants also reserve the right to present appropriate arguments and/or evidence to establish patentability over the references, should one or more of the references be applied against the claims of the present application.

Applicants request that the Examiner independently determine those items which the Examiner would consider the most pertinent of all the references cited herein.

This Supplemental Information Disclosure Statement is filed before the mailing of any of a final action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application. The \$180.00 fee set forth in 37 C.F.R. 1.17(p) is being charged to the undersigned's credit card. Any deficiency or overpayment should be charged or credited to Deposit Account No. 02-2275. Accordingly, this document complies with the requirements of 37 C.F.R. Section 1.97(c). It is respectfully requested that the reference cited in the accompanying form PTO-1449 be considered and made of record.

Respectfully submitted,

LUCAS & MERCANTI, LLP

A handwritten signature in black ink, appearing to read 'M. Mercanti', is written over a horizontal line.

Michael N. Mercanti  
Registration No. 33,966

LUCAS & MERCANTI, LLP  
475 Park Avenue South  
New York, New York 10016  
212-661-8000

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09887496
	Filing Date		2001-06-22
	First Named Inventor	Banerjee, Partha S.	
	Art Unit	1617	
	Examiner Name	KANTAMNENI, Shobha	
	Attorney Docket Number	1121.0206-US1	

## U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6667344		2003-12-23	Banerjee et al.	
	2	6814593		2004-11-09	Banerjee et al.	
	3	7070800		2006-07-04	Bechtold-Peters	
	4	6448296		2002-09-10	Yasueda et al.	
	5	6632842		2003-10-14	Chaudry et al.	
	6	6702997		2004-03-09	Chaudry et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

## U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
-------------------	---------	--------------------	------------------------	------------------	---	--

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09887496
Filing Date	2001-06-22
First Named Inventor	Banerjee, Partha S.
Art Unit	1617
Examiner Name	KANTAMNENI, Shobha
Attorney Docket Number	1121.0206-US1

1	20020151598	2002-10-17	Banerjee et al.
2	20030055026	2003-03-20	Banerjee et al.
3	20040109826	2004-06-10	Malladi et al.
4	20040110845	2004-06-10	Malladi et al.
5	20040023935	2004-02-05	Banerjee et al.
6	20030124063	2003-07-03	Chaudry et al.
7	20050009923	2005-01-13	Banerjee et al.

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	0616525	EP		1995-09-27			<input type="checkbox"/>
	2	19847970	DE		2000-04-20			<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09887496
Filing Date		2001-06-22
First Named Inventor	Banerjee, Partha S.	
Art Unit	1617	
Examiner Name	KANTAMNENI, Shobha	
Attorney Docket Number	1121.0206-US1	

3	97/47286	WO	1997-12-18	<input type="checkbox"/>
4	01/89492	WO	2001-11-29	<input type="checkbox"/>
5	99/65464	WO	1999-12-23	<input type="checkbox"/>
6	02/83079	WO	2002-10-24	<input type="checkbox"/>
7	00/23065	WO	2000-04-27	<input type="checkbox"/>
8	05/007142	WO	2005-01-27	<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Becker et al., "Formoterol, a new long-acting selective b2-adrenergic receptor agonist: Double-blind comparison with salbutamol and placebo in children with asthma" J. Allergy Clin. Immunol. 84:891-895 (1989)	<input type="checkbox"/>
	2	Daugbjerg et al. "Duration of action of formoterol and salbutamol dry-powder in halation in prevention of exercise-induced asthma in children" Acta Paediatr. 85: 684-687 (1996)	<input type="checkbox"/>
	3	Derwent#013132855, WPI Acc No.:200-304726/200027, for German Patent De 19847970, "Stable concentrated liquid formulation of inhalable drug, e.g. formoterol or salbutamol, in solution or suspension medium, used after dilution for treatment of respiratory disorders by inhalation"	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09887496
Filing Date	2001-06-22
First Named Inventor	Banerjee, Partha S.
Art Unit	1617
Examiner Name	KANTAMNENI, Shobha
Attorney Docket Number	1121.0206-US1

4	Ida "Comparison of the Action of BD 40A and some Other b-Adrenoceptor Stimulants on the Isolated Trachea and Atria of the Guinea Pig" <i>Arzneim.-Forsch. (Drug Res)</i> 26:839-842 (1976)	<input type="checkbox"/>
5	Ida "Cardiorespiratory Activities of 3-Formylamino-4-hydroxy-a-(N-1-methyl-2-p-methoxyphenethylaminomethyl) benzylalcohol-hemifumarate (BD 40A) and some other b-Adrenoceptor Stimulants in Conscious Guinea Pigs" <i>Arzneim.-Forsch. (Drug Res.)</i> 26:1337-1340 (1976)	<input type="checkbox"/>
6	Kamimura et al. "Quantitative Determination of the b-adrenoceptor stimulant Formoterol in Urine by Gas Chromatograph mass Spectrometry" <i>J. Chrom.</i> 229:337-345 (1982)	<input type="checkbox"/>
7	Lebecque et al. "Effet d'une dose unique de formoterol par voie daerosol-doseur chez l'enfant asthmatique" <i>Rev. Mal. Resp.</i> 11:47-50 (1994)	<input type="checkbox"/>
8	Lofdahl et al., "Formoterol Fumarate, a new b2-adrenoceptor agonist" <i>Allergy</i> 44:264-271 (1989)	<input type="checkbox"/>
9	Maesen et al. "Formoterol Suspension Aerosol" <i>Chest</i> 102:1544-1549 (1992)	<input type="checkbox"/>
10	Maesen et al. "The Effect of maximal Doses of Formoterol and Salbutmaol from a metered Dose Inhaler on Pulse Rates, ECG, and Serum Potassium Concentrations" <i>Chest</i> 99:1367-1373 (1991)	<input type="checkbox"/>
11	Maesen et al. "Formoterol as Dry Powder Inhalation" <i>Chest</i> 101:1376-1381 (1992)	<input type="checkbox"/>
12	Miller et al. "Chronic Effects of the Novel Glucocorticosteroid RPR 106541 Administered to Beagle Dogs by Inhalation" <i>Toxic. Path.</i> 28:226-236 (2000)	<input type="checkbox"/>
13	Murase et al. "New b-Adrenoreceptor Stimulants. Studies on 3-Acylamino-4-hydroxy-a-(N-substituted aminomethyl) benzyl Alcohols" <i>Chem Pharm. Bull.</i> 26:1368-1377 (1977)	<input type="checkbox"/>
14	Sasaki et al. "Desposition and metabolism of formoterol fumarate, a new bronchodilator, in rats and dogs" <i>Xenobiotic</i> 12:803-809 (1998)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09887496
Filing Date	2001-06-22
First Named Inventor	Banerjee, Partha S.
Art Unit	1617
Examiner Name	KANTAMNENI, Shobha
Attorney Docket Number	1121.0206-US1

15	Scheen "Pharma-Clinics le Medicament du Mois le formoterol (Oxis Turbohaler)" Rev. Med. Liege 53:11:715-718 (1998)	<input type="checkbox"/>
16	Sovijarvi et al. "Preventive Effects of Inhaled Formoterol and Salbutamol on Histamine-Induced Bronchoconstriction - A Placebo-Controlled Study" Respiration 59:279-282 (1999)	<input type="checkbox"/>
17	Stevens et al. "Use of the Steroid Derivative RPR 106541 in Combination with Site-Directed Mutagenesis for Enhanced Cytochrome P-450 3A4 Structure/Function Analysis" J. Pharma. Exp. Ther. 290:594-602 (1999)	<input type="checkbox"/>
18	Van den Berg et al. "Evaluation of different doses of formoterol from a newly developed powder inhalation device in asthmatic patients" Fundam. Clin. Pharmacol. 9:593-603 (1995)	<input type="checkbox"/>
19	Wallin et al., "Time course and duration of bronchodilation with formoterol dry powder in patients with stable asthma" Thorax 48:611-614 (1993)	<input type="checkbox"/>
20	Yokoi et al. "The Development of a Radioimmunoassay for Formoterol" Life Sciences 33:1665-1672 (1983)	<input type="checkbox"/>
21	Yoshida et al., "Acute, Subacute and Chronic toxicity Studies of a Bronchodilator, Formoterol Fumarate (BD 40)" Oyo Yakuri, 26(5), 811-29 (1983)	<input type="checkbox"/>
22	Derwent WPI Acc No.: 2000-304726 for PCT Patent Application WO 00/23037, "Stable concentrated liquid formulation of inhalable drug, e.g. formoterol or salbutamol, in solution or suspension medium, used after dilution for treatment of respiratory disorders by inhalation"	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	09887496
Filing Date	2001-06-22
First Named Inventor	Banerjee, Partha S.
Art Unit	1617
Examiner Name	KANTAMNENI, Shobha
Attorney Docket Number	1121.0206-US1

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).


**OR**

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2007-06-27
Name/Print	Michael N. Mercanti	Registration Number	33,966

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.